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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

BEN CHEN et al.

Serial No.: 08/169,293

Group Art Unit:

Filing Date: 17 December 1993

Examiner: Unassigned

OOM

A METHOD OF PREVENTING

DEPLETION OF NON-

AUTOLOGOUS HEMATOPOIETIC CELLS AND ANIMAL MODEL SYSTEMS FOR USE THEREOF

> INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR § 1.97

SPECIAL PROCESSING AND CORRESPONDENCE BRANCH

The Honorable Commissioner of Patents and Trademarks Washington, D.C.

Dear Sir:

The information listed below, which may be material to the examination of the above-identified application, was disclosed to the Examiner throughout the application as The information is listed below in the originally filed. same order that it appears in the application as originally Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

Mosier et al., "Transfer of a functional human immune system to mice with severe combined immunodeficiency" Nature (1988) 335:256-259.

Kamel-Reid et al., "Engraftment of immune-deficient mice with human hematopoietic stem cells" <u>Science</u> (1988) 242:1706-1709.

McCune et al., "The SCID-hu mouse: murine model for the analysis of human hematolymphoid differentiation and function" <u>Science</u> (1988) <u>241</u>:1632-1639.

Namikawa et al., "Long-term human hematopoiesis in the SCID-hu mouse" J. Exp. Med. (1990) 172:1055-1063.

Kyoizumi et al., "Implantation and maintenance of functional human bone marrow in SCID-hu mice" Blood (1992) 79:1704-1711.

Lapidot et al., "Cytokine stimulation of multilineage hematopoiesis from immature human cells engrafted in SCID mice" <u>Science</u> (1992) <u>255</u>:1137-1141.

Krowka et al., "Human T cells in the SCID-hu mouse are phenotypically normal and functionally competent" <u>J.</u>

<u>Immunol.</u> (1991) <u>146</u>:3751-3756.

Vandekerckhove et al., "Clonal analysis of the peripheral T cell compartment of the SCID-hu mouse" <u>J. Immunol.</u> (1991) 146:4173-4179.

Vandekerckhove et al., "Human hematopoietic cells and thymic epithelial cells induce tolerance via different mechanisms in the SCID-hu mouse thymus" <u>J. Exp. Med.</u> (1992) <u>175</u>:1033-1043.

Péault et al., "Lymphoid reconstitution of the human fetal thymus in SCID mice with CD34<sup>+</sup> precursor cells" <u>J. Exp. Med.</u> (1991) <u>174</u>:1283-1286.

Baum et al., "Isolation of a candidate human hematopoietic stem-cell population" <a href="Proc. Natl. Acad. Sci. USA">Proc. Natl. Acad. Sci. USA</a> (1992) 89:2804-2808.

McCune et al., "Suppression of HIV infection in AZT-treated SCID-hu mice" Science (1990) 247:564-566.

Lockwood, "Immunological functions of the spleen" <u>Clin.</u> <u>Haematol.</u> (1983) <u>12</u>:449-465.

Van Rooijen et al., "Elimination of phagocytic cells in the spleen after intravenous injection of liposome-encapsulated dichloromethylene diphosphonate" <u>Cell Tiss. Res.</u> (1984) 238:355-358.

Van Rooijen et al., "In vivo Elimination of Macrophages in Spleen and Liver, Using Liposome-Encapsulated Drugs: Methods and Applications" (John Wliey and Sons, Chichester, 1988).

Gregoriadis et al., eds., <u>Targeting of Drugs</u>, Plenum Press, New York (1982). A title page and table of contents is enclosed herewith.

Van Rooijen et al., "Macrophage subset repopulation in the spleen: Differential kinetics after liposome-mediated elimination" <u>J. Leuk. Biol.</u> (1989) <u>45</u>:97-104.

Oi et al., "Fluorescent phycobiliprotein conjugates for analyses of cells and molecules" <u>J. Cell Biol.</u> (1982) 93:981-986.

Boorsma et al., "Periodate or glutaraldehyde for preparing peroxidase conjugates?" J. Immunol. Met. (1979) 30:245-255.

Eikelenboom, "Characterization of non-lymphoid cells in the white pulp of the mouse spleen: An in vivo and in vitro study" Cell Tiss. Res. (1978) 195:445-460.

Delemarre et al., "The *in situ* immune response in popliteal lymph nodes of mice after macrophage depletion.

Differential effects of macrophages on thymus-dependent and thymus-independent immune responses" <u>Immunobiol</u>. (1990) 180:395-404.

Van Rooijen, "The liposome-mediated macrophage 'suicide' technique" J. Immunol. Meth. (1989) 124:1-6.

The references above are summarized throughout the application as originally filed. The summaries contain what the undersigned believes to be the salient aspects of the cited references. They are not intended to be a comprehensive statement of the relevance of the references to the subject inv ntion.

The reference cited as Van Rooijen (1988) is not enclosed but will be provided in due course. The following references are discussed in the specification but may not be available as prior art. Copies of these references are supplied for the Examiner's convenience.

Kyoizumi et al., "Preclinical analysis of cytokine therapy in the SCID-hu mouse" <u>Blood</u> (1993) <u>81</u>:1479-1488.

Namikawa et al., "Growth of human myeloid leukemias in the human marrow environment of SCID-hu mice" <u>Blood</u> (1993) 82:2526-2536.

Vandekerckhove et al., "Thymic selection of the human T cell receptor  $V\beta$  repertoire in SCID-hu mice" <u>J. Exp. Med.</u> (1992) 176:1619-1624.

Baccala et al., "Bacterial superantigens mediate T cell deletions in the mouse severe combined immunodeficiency-human liver/thymus model" <u>J. Exp. Med.</u> (1993) <u>177</u>:1481-1485.

Bonyhadi et al., "HIV induces thymus depletion in vivo" Nature (1993) 363:728-732.

Aldrovandi et al., "The SCID-hu mouse as a model for HIV-1 infection" Nature (1993) 363:732-736.

Kraal et al., "Systemic elimination of macrophages using liposomes does not prevent the induction of type I diabetes" <a href="Int.Arch.Allergy Immunol.">Int. Arch. Allergy Immunol.</a> (1993) 100:115-120.

This Information Disclosure Statement is submitted before receipt of the first Office Action on the Merits. Therefore, the applicants believe that no fee is due. However, the Commissioner is hereby authorized to charge any fees which may be required by this paper to Deposit Account Number 03-1952.

Applicants would appreciate the Examiner's initialling and returning the Form PTO-1449, indicating that the references have indeed been considered and made of record herein.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

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